Health informatics - International patient summary (ISO 27269:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 27269:2022 sisaldab Euroopa standardi EN ISO 27269:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 27269:2022 consists of the English text of the European standard EN ISO 27269:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 30.03.2022.	Date of Availability of the European standard is 30.03.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Health informatics - International patient summary (ISO 27269:2021)

Informatique de santé - Résumé international du dossier médical du patient (ISO 27269:2021)

Medizinische Informatik - Die internationale Patienten-Kurzakte (ISO 27269:2021)

This European Standard was approved by CEN on 20 March 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 27269:2022 E

European foreword

The text of ISO 27269:2021 has been prepared by Technical Committee ISO/TC 215 "Health informatics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 27269:2022 by Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2022, and conflicting national standards shall be withdrawn at the latest by September 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 17269:2019.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 27269:2021 has been approved by CEN as EN ISO 27269:2022 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by European Committee for Standardization (CEN) (as EN 17269:2019) and was adopted, with the following modifications by Technical Committee ISO/TC 215, *Health informatics*.

— changed "this European Standard" to "this document";

— changed any "EN ISO xxxx" references to "ISO xxxx" references;

— changed "section" to "Clause", if appropriate;

— definitions of IPS terms in body of text were moved to Clause 3;

— Clause 3 was reorganized based upon existing ContSys hierarchy;

— more description on conformance, data blocks, more examples in concept values and updated definition citations given in response.

— on implementation evidence from HL7 FHIR ®[1)], the requirement to require/enable the expression of the name data element as a single string as well as the structured representation to permit the natural way of expression in some eastern countries and facilitate cross-border use;

— 'Healthcare Provider' became an Attribute Collection data block, defined and positioned in Clause 3 rather than be treated as a data type.

— complete editorial revision.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

1) HL7 FHIR is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Introduction

The goal of this document is to deliver a single, common International Patient Summary (IPS), comprising core content.

This document achieves that goal by defining a minimal yet non-exhaustive data set and its associated business rules. This document is implementation independent yet still supportive of any implementation by providing formal definition and clear description of a small data set. The primary input to the data set is the second revision of the European eHealth Network's (eHN) data set[1], which, in turn, builds upon significant clinical input from the European Patients-Smart Open Services (epSOS) pilot project[2].

This document defines the IPS, with the initial focus upon unplanned care across national borders. Starting from this focus, and building upon it, the specification is intended to be used and be useful in national and local applications and also to be supportive of both planned and unplanned care. The IPS is designed to provide clinical information to assist care across any jurisdictional border (e.g. local, regional, state/provincial, national). It emphasizes the data required and the associated business rules to support use and the necessary conformance of the use case for an international patient summary. Even though the data set is relatively small, there is no expectation that the full data set has to be realized for a conformant implementation or conformant specification to be produced. Such artefacts need not specify all the optional IPS elements, given that they should assure the openness and extensibility of the derived model.

The data set described is intended for global use beginning with a shared vision[1] from a collaboration between CEN /TC 251 and HL7®[2)], but now involving five Standard Development Organizations each contributing artefacts to support the single solution IPS going forward. From the IPS reference model it is possible to derive a number of compliant logical models that constrain it, and these lead to implementable specifications, such as the IPS CDA and FHIR Implementation Guides. These guides are formalized in the HL7 CDA IG®[2)] and HL7 IG®[2)] and in the IHE IPS®[2)] profile. The IPS Dataset is not bound by any terminology, although it does anticipate the use of the IDMP standard for medication. SNOMED®[3)] International has provided a Global Patient Set for the IPS implementations. CEN has produced a separate Technical Specification[3], that provides a European-specific guideline for IPS implementation, which can also be used as an example for other jurisdictions.

The 'International' element of the IPS emphasizes the need to provide generic solutions for global application moving beyond a particular region or country, consequently, wherever possible, reference is made to international standards, rather than local ones. However, different international contexts will offer a variety of requirements that need to be considered to ensure that patient safety is not compromised. The IPS is underpinned by ISO 13940, which is a system of concepts to support continuity of care[4] and uses those concepts in the initial IPS scenario, which is fully described in Annex A.

This document focuses upon the overall structure of the patient summary as well as the individual data elements that comprise it. The layout of this document (see Table 1) uses a hierarchy of levels (H0 to H7) to facilitate more detailed description with the purpose of supporting consistent implementation of the data set. The level 'H0' describes the IPS Document as a whole, whilst levels H1-H7 describe the IPS Data Blocks with attributes. Descriptors are added to each data element to better define the characteristics. The 'H0' level document structure and constraints will be described first, the components start with H1 (e.g. IPS Sections, IPS Attribute Collections).

2) HL7, HL7 CDA IG, HL7 IG and HL7 IPS are the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the products named.

3) SNOMED is the registered trademark of International Health Terminology Standards Development Organization. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Table 1 — Description of IPS Data Set concepts and their hierarchical relationships

Descriptive hierarchy	H0	H1	H2 – H7
IPS Data Transfer Object	IPS Document	All possible IPS and the Non-IPS components are identified	Further detail is provided within the IPS Data Blocks' clauses
IPS Data Blocks	-	Individual IPS Sections, IPS Attribute Collections	Hierarchical description of data elements

The ordering of the IPS Data Blocks in this document is within three broad categories of Non-Clinical Data, Clinical Data and Metadata. This follows the eHDSI patient summary deployment project[5] and here is used purely to help presentation. However, in practice it is recognized that individual attributes might appear in different categories depending on dynamic use rather than static classification.

As the amount of information for each data element is variable, and can be extensive, this document presents the information using a table with descriptors for each IPS Data Block; the table provides an overview of the hierarchical structure and its requirement with explicit links to more details using a consistent set of descriptors. Those attributes in the table that do not have a link to further detail are either self-explanatory or explained by the hierarchical context. Note, the order of sibling attributes is arbitrary and has no implication for implementations of this document. The name of the element is contextualized by the hierarchy so as to avoid any misunderstanding. For example, the term 'Device Type' will be used rather than just "Type" albeit that it refers to a data element positioned within the Medical Device IPS Data Block.

Health informatics — International patient summary

1 Scope

This document defines the core data set for a patient summary document that supports continuity of care for a person and coordination of their healthcare. It is specifically aimed at supporting the use case' scenario for 'unplanned, cross border care' and is intended to be an international patient summary (IPS). Whilst the data set is minimal and non-exhaustive, it provides a robust, well-defined core set of data items. The tight focus on this use case also enables the IPS to be used in planned care. This means that both unplanned and planned care can be supported by this data set within local and national contexts, thereby increasing its utility and value.

It uses the European Guideline from the eHN as the initial source for the patient summary requirements, then takes into consideration other international patient summary projects to provide an interoperable data set specification that has global application.

This document provides an abstract definition of a Patient Summary from which derived models are implementable. Due to its nature therefore, readers should be aware that the compliance with this document does not imply automatic technical interoperability; this result, enabled by this document, can be reached with the conformity to standards indicated in the associated technical specification and implementation guides.

This document does not cover the workflow processes of data entry, data collection, data summarization, subsequent data presentation, assimilation, or aggregation. Furthermore, this document does not cover the summarization act itself, i.e. the intelligence/skill/competence that results in the data summarization workflow.

It is not an implementation guide that is concerned with the various technical layers beneath the application layer. Implementation guidance for specifically jurisdictional concerns, e.g. Directives, terminologies, formats, etc., an example is specified in the associated Technical Specification[3].

In particular, representation by various coding schemes, additional structures and terminologies are not part of this document. Terminology and its binding are addressed in Reference [3]. The Identification of Medicinal Products standards (abbreviated to IDMP) are the recommended target for the Medication Summary related to this document but, prior to IDMP's full implementation in practice, this IPS standard cannot insist in its use at this point in time and recognizes that interim schemes might be necessary until IDMP becomes established as a norm.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/